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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: FODSTAD ET AL. Examiner: B. NGUYEN
Serial No.: 08/403,844 Group Art Unit: 1641
Filed: APRIL 18, 1995 Docket: 7885.33USF1
CPA FILED: JUNE 23, 1998
Due Date: FEBRUARY 28, 1999
Title: METHOD FOR DETECTION OF SPECIFIC TARGET CELLS IN SPECIALIZED OR MIXED CELL POPULATION AND SOLUTIONS CONTAINING MIXED CELL POPULATIONS

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this Transmittal Letter and the paper, as described herein, are being deposited in the United States Postal Service, as first class mail, with sufficient postage, in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on February 25, 1999.

By: *Charles B. Bland*
CANDIS B. BLAND

RESPONSE TO SPECIES ELECTION REQUIREMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

In response to the Office Action mailed September 28, 1998, Applicants request entry of the following species election and consideration of the remarks below.

Election

The Office Action mailed September 28, 1998 was in the nature of a species election requirement. By way of response, Applicants elect the species described below. Applicants reserve the right to pursue the non-elected claims or species by appropriate means in the future, for example, by a divisional or continuation application, should they so desire.

The Examiner asserted that Applicants are required to elect one method of characterizing the separated cells from the methods of counting, analysis of DNA, mRNA or protein, PCR, and cell culture growth. Applicants respectfully submit that it would not be overly burdensome to search methods including counting, analysis of DNA, mRNA or protein, PCR, and cell culture growth, and that these methods are not patentably distinct. If the Examiner maintains this election requirement, Applicants elect counting, which is recited in claim 64.

The Examiner asserted that Applicants are required to elect one moiety against which the claimed antibody or fragment is directed. The dependent claims recite as specific moieties receptors, integrins, epitopes, cancer antigens, and high molecular weight antigens. Applicants respectfully submit that it would not be overly burdensome to search compositions including these moieties, and that these moieties are not patentably distinct. If the Examiner maintains this election requirement, Applicants elect cancer antigens.

The Examiner asserted that Applicants are required to elect a method of detecting a target cell. The choices are: 1) using an antibody or a fragment directed to an antigen expressed on the target cell; and 2) using antibodies or fragments directed to two different antigens expressed on the target cell. Applicants respectfully submit that it would not be overly burdensome to search both of these methods, and that these methods are not patentably distinct. If the Examiner maintains this election requirement, Applicants elect using an antibody or a fragment directed to an antigen expressed on the target cell.

Applicants acknowledge the Examiner's indication that claims 22-25, 28, 29, 33-38, 46-48, 51, 59-62, 66, 67, 69, 78, 87, 88, and 92 are generic and that the species election requirement will come into effect only if no generic claim is found allowable.

The Widder Reference

The Examiner asserts that the coated beads of claim 1 are obvious with respect to Widder et al. (EP 016552) and therefore lack a special technical feature. Applicants respectfully traverse this objection.

The Widder reference cited by the Examiner uses Protein A to bind antibodies to magnetic particles. The Protein A binding is required to properly orient the antibodies (Widder, Col.3, lines 31-43). Furthermore, Protein A binds to the Fe portion of an antibody. This binding, however, lacks the high level of specificity required of the present invention. Additionally, Protein A will also show specific binding to B-cells and plasma cells, both of which are non-target-cells according to the present method. The level of specificity in the present invention is so high that no person skilled in the art of the present invention would apply the Protein A/Ig system disclosed in Widder to arrive at the method presently disclosed.

The Applicants' invention is distinct from the disclosure of Widder in other manners. The Applicants' invention does not require precoating the paramagnetic particles or beads with Protein A. Widder differs from the instant invention in failing to teach the use of enzyme labels and an avidin/biotin binding system. Widder also does not teach using fixatives to pretreat the sample. Hence, Widder neither teaches nor suggests the claimed invention

The Examiner is invited to contact Applicants's undersigned representative at the telephone number listed below, if the Examiner believes that prosecution of this application can be advanced thereby.

Respectfully submitted,

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